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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/677,967	10/02/2003	Anke Esperester	01-1556	9274

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MICHAEL P. MORRIS
BOEHRINGER INGELHEIM CORPORATION
900 RIDGEBURY ROAD
P. O. BOX 368
RIDGEFIELD, CT 06877-0368

EXAMINER	
KIM, JENNIFER M	

ART UNIT	PAPER NUMBER
1617	

MAIL DATE	DELIVERY MODE
03/27/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/677,967	ESPERESTER ET AL.	
	Examiner	Art Unit	
	Jennifer Kim	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 February 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8 and 9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8 and 9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on February 27, 2008 has been entered.

Action Summary

The rejection of claims 7-11 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 19 of U.S. Patent No. 6,663,889 B1 is hereby expressly **withdrawn** in view of Applicants' amendment.

The rejection of claim 7 under 35 U.S.C. 102(b) as being anticipated by Weiser (2000) is hereby expressly **withdrawn** in view of Applicants' amendment.

The rejection of claims 7-11 under 35 U.S.C. 102(b) as being anticipated by Maerz et al. (WO 01/05378A1) (see English translation U.S.Patent No. 6,663,889B1) is hereby expressly **withdrawn** in view of Applicants' amendment.

The rejection of claims 7-11 under 35 U.S.C. 102(e) as being anticipated by Maerz et al. (U.S.Patent No. 6,663,889 B1) is hereby expressly **withdrawn** in view of Applicants' amendment.

Response to Arguments

Applicants' arguments with respect to claims 8 and 9 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weiser (2000) of record in view of Maerz et al. (WO 01/05378A1) (see English translation U.S.Patent No. 6,663,889B1) of record and further in view of Ward et al. (U.S.Patent No. 3,914,433).

Weiser teaches that Ambroxol is well established in the treatment of inflammatory diseases of the respiratory tract. Weiser teaches that Ambroxol can be used as an effective treatment of **sore throat**. (abstract).

Weiser et al. lack a flavoring, a lubricant, a matrix material, a sweetening agent and a poyethyleneglycol and treatment of "inflamed pharynx".

Maerz et al. teach a tablet for sucking containing the active substance ambroxol and having improved properties brought by peppermint flavor, saccharin, sorbitol (sugar alcohol), polyethylene glycol (Macrogol 6000) and hydrated magnesium silicate. (abstract, examples on pages 5-6) (abstract, examples in column 3 and claims, English version). Maerz et al. teach such composition has improved properties. (abstract).

Ward et al. teach that a sore throat is the pain associated with inflammation of the oral pharynx. (column 1, lines 13-15).

It would have been obvious to one of ordinary skill in the art to employ ambroxol composition taught by Maerz et al. as an anti-inflammatory agent to treat the inflamed pharynx in a patient because Weiser teaches that Ambroxol is well established in the treatment of inflammatory disease including sore throat which is a discomfort or pain associated with inflammation of the oral pharynx in view of Ward et al. and because Maerz et al's composition comprising ambroxol has improved properties that contains the active substance ambroxol. One would have been motivated to make such a modification in order to achieve an expected benefit of Maerz et al's improved properties that contains the active substance ambroxol having effectiveness in treating inflammation of the oral pharynx (sore throat). There is a reasonable expectation of successfully treating inflamed pharynx with ambroxol because ambroxol is well established in the treatment of inflammatory dieses such as sore throat and ambroxol composition comprising such excipients are known to provide improved properties of the active agent ambroxol in view of Maerz et al.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 8 and 9 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 19 of U.S. Patent No. 6,663,889 B1 in view of Weiser (2000) of record.

Instant claims are drawn to a method for treating an inflamed pharynx comprising the step of applying to the inflamed pharynx a pharmaceutical composition comprising ambroxol hydrochloride as an anti-inflammatory agent, a flavoring, a lubricant, a matrix material, a sweetening agent and a polyethylene glycol to treat the inflamed pharynx in a suckable tablet.

Patented claim is drawn to a method of administering ambroxol to a patient comprising administering to the patient a tablet for sucking comprising a suckable tablet comprising ambroxol, a sugar alcohol a matrix material a pharmaceutically acceptable

laminar silicate and a polyethylene glycol, optionally together with one or more other pharmaceutical excipients, taste enhancers or flavorings.

The difference between instant claims and the patented claim is the patient population to be treated.

Weiser et al. teach that ambroxol is effective in treating inflammatory disorder such as sore throat (inflamed pharynx).

Therefore, it would have been obvious to one of ordinary skill in the art to employ the method of administering ambroxol composition taught by the patent to a patient having inflamed pharynx because Weiser et al. teach that ambroxol composition is effective in treating inflammatory disorder such as sore throat (inflamed pharynx) and because such method is obviously required in order to treat inflamed pharynx. One would have been motivated to make such a modification in order to achieve an expected benefit of treating inflamed pharynx by method of administering ambroxol composition taught by the patent.

None of the claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jennifer Kim/
Primary Examiner, Art Unit 1617

Jmk
March 20, 2008